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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/151,885	09/11/1998	JAMES C. COSTIN	98-WL-1	8455

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EXAMINER	
WHITE, EVERETT NMN	
ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 07/29/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/151,885	COSTIN, JAMES C.	
	Examiner	Art Unit	
	EVERETT WHITE	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 23, 2003 has been entered.

2. The amendment filed June 23, 2003 has been received, entered and carefully considered. The amendment affects the instant application accordingly:

(A) Claims 7-17 have been canceled.
(B) New Claims 18-35 have been added.
(C) Comments regarding Office Action have been provided drawn to
  (a) 112, 1st para. rejection, which has been withdrawn;
  (b) 102(b) rejection, rendered moot by new ground of rejection over newly cited reference;
  (c) 103(a) rejection, rendered moot by new ground of rejection over newly cited reference.

3. Claims 18-35 are pending in the case.

4. The text of those sections of title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

5. Claims 18 and 20-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Jones et al (Journal of Applied Bacteriology, "The Effects of Three Non-Antibiotic, Antimicrobial Agents on the Surface Hydrophobicity of Certain Micro-organisms Evaluated by Different Methods", 1991, 71, 218-227, newly cited).

Applicants claim a method for reducing the adherence of staphylococcus saprophyticus to epithelial cells which comprises treating said staphylococcus saprophyticus or said epithelial cells with 4,4'-methylenebis(tetrahydro-1,2,4 thiadiazine-

1,1-dioxide). Additional limitations in the dependent claims include the method wherein the epithelial cells are buccal epithelial cells, the method wherein said staphylococcus saprophyticus is a urine isolate, and the method further comprising about a thirty minute contact time.

The Jones et al reference discloses the use of Taurolidine to reduce the adherence of Staphylococcus saprophyticus to epithelial cells, which anticipates the method of instant Claim 18 (see abstract). Taurolidine is the common name for 4,4'-methylenebis(tetrahydro-1,2,4 thiadiazine-1,1-dioxide). The Jones et al reference discloses that the Staphylococcus saprophyticus thereof was isolated from urine (see page 219, 1st column, lines 31 and 32), which anticipates the urine isolated Staphylococcus saprophyticus of the instant claims. The Jones et al reference also discloses the treatment of human buccal epithelial cells (see Table 3 on page 226), which anticipates the subject matter of instant Claim 20. The Jones et al reference further discloses that Taurolidine was supplied as 2.0% w/v aqueous solution, which anticipates the concentration of the Taurolidine set forth in the instant claims. With regard to the disclosure of a thirty minute contact time set forth in the instant claims, Applicants are reminded that the limitation of a process with respect to ranges of pH, time and temperature does not impart patentability to a process when such values are those, which would be determined by one skilled in the art in achieving optimum operation of the process. *In re Mostovych et al.* (CCPA 1964) 339 F2d 455, 144 USPQ 38; *In re Aller et al.* (CCPA 1955) 220 F2d 454, 105 USPQ 233. The description of the method given above for the Jones et al reference anticipates the instantly claimed method of reducing the adherence of Staphylococcus saprophyticus to epithelia cells.

6. Applicant's arguments with respect to Claims 18 and 20-23 have been considered but are moot in view of the new ground of rejection.

7. Claims 25-28, 30-32, 34 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Jones et al (Journal of Applied Bacteriology, "The Effects of Three Non-Antibiotic, Antimicrobial Agents on the Surface Hydrophobicity of Certain Micro-organisms Evaluated by Different Methods", 1991, 71, 218-227, newly cited).

Applicants claim a method for reducing the adherence of microorganisms to epithelial cells which comprises treating the microorganisms or epithelial cells with 4,4'-methylenebis(tetrahydro-1,2,4 thiadiazine-1,1-dioxide) at a concentration of about 0.05% w/v to about 2.0% w/v for about a thirty minute contact time. Additional limitations in the dependent claims include specific microorganisms; where the microorganisms were isolated from; and specific epithelial cells.

The Jones et al reference discloses the use of Taurolidine to reduce the adherence of Escherichia coli, Staphylococcus saprophyticus, Staphylococcus epidermidis and Candida albicans to epithelial cells (see abstract), whereby Taurolidine is the common name for 4,4'-methylenebis(tetrahydro-1,2,4 thiadiazine-1,1-dioxide). The Jones et al reference discloses that the Escherichia coli, Staphylococcus saprophyticus, and Staphylococcus epidermidis were isolated from urine (see page 219, 1st column, lines 31 and 32), which anticipates the urine isolated Escherichia coli of the instant claims. The Jones et al reference also sets forth the effect of Taurolidine treatments of Candida albicans, Excherichia coli, and Staphylococcus saprophyticus on the subsequent adherence to human buccal epithelia cells in vitro (see Table 3 on page 226), which anticipates the subject matter of instant Claims 26 and 30. The Jones et al reference further discloses that Taurolidine was supplied as 2.0% w/v aqueous solution, which anticipates the concentration of the Taurolidine set forth in the instant claims. With regard to the disclosure of a thirty minute contact time set forth in the instant claims, Applicants are reminded that the limitation of a process with respect to ranges of pH, time and temperature does not impart patentability to a process when such values are those, which would be determined by one skilled in the art in achieving optimum operation of the process. *In re Mostovych et al.* (CCPA 1964) 339 F2d 455, 144 USPQ 38; *In re Aller et al.* (CCPA 1955) 220 F2d 454, 105 USPQ 233. The description of the method given above for the Jones et al reference anticipates the instantly claimed method of reducing the adherence of microorganisms to epithelia cells.

8. Applicant's arguments with respect to Claims 25-28, 30-32, 34 and 35 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

9. Claim 18-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones et al (Journal of Applied Bacteriology, "The Effects of Three Non-Antibiotic, Antimicrobial Agents on the Surface Hydrophobicity of Certain Micro-organisms Evaluated by Different Methods", 1991, 71, 218-227, newly cited) in view of Gorman et al (Journal of Clinical Pharmacy and Therapeutics, vol. 12, pages 393-399 (1987), already of record).

Applicants claim a method for reducing the adherence of microorganisms to epithelial cells which comprises treating the microorganisms or epithelial cells with 4,4'-methylenebis(tetrahydro-1,2,4 thiadiazine-1,1-dioxide) at a concentration of about 0.05% w/v to about 2.0% w/v for about a thirty minute contact time. Additional limitations in the dependent claims include specific microorganisms; where the microorganisms were isolated from; and specific epithelial cells.

The Jones et al reference discloses the use of Taurolidine to reduce the adherence of Escherichia coli, Staphylococcus saprophyticus, Staphylococcus epidermidis and Candida albicans to epithelial cells (see abstract), whereby Taurolidine is the common name for 4,4'-methylenebis(tetrahydro-1,2,4 thiadiazine-1,1-dioxide). The Jones et al reference discloses that the Escherichia coli, Staphylococcus saprophyticus, and Staphylococcus epidermidis were isolated from urine (see page 219, 1st column, lines 31 and 32), which encompass the urine isolated Escherichia coli of the instant claims. The Jones et al reference also sets forth the effect of Taurolidine treatments of Candida albicans, Escherichia coli, and Staphylococcus saprophyticus on the subsequent adherence to human buccal epithelia cells in vitro (see Table 3 on page 226), which embraces the subject matter of instant Claims 26 and 30. The Jones et al reference further discloses that Taurolidine was supplied as 2.0% w/v aqueous solution, which embraces the concentration of the Taurolidine set forth in the instant claims. With regard to the disclosure of a thirty minute contact time set forth in the instant claims, Applicants are reminded that the limitation of a process with respect to ranges of pH, time and temperature does not impart patentability to a process when such values are

those, which would be determined by one skilled in the art in achieving optimum operation of the process. *In re Mostovych et al.* (CCPA 1964) 339 F2d 455, 144 USPQ 38; *In re Aller et al.* (CCPA 1955) 220 F2d 454, 105 USPQ 233. The method of the instantly claimed invention differs from the method of the Jones et al reference by disclosing in instant Claims 19 and 29 that the epithelial cells are uropithelia cells. However, the Gorman et al reference, which discloses Taurolidine as having anti-adherence activity for oral isolate of Candida albicans to human buccal epithelial cells, shows that Taurolidine is also effective for urine isolate of Escherichia coli to human uroepithelial cells. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the employment of Taurolidine to reduce the adherence of Escherichia coli to epithelial cells as set forth in the Jones et al reference with a method that employs Taurolidine to reduce the adherence of Escherichia coli to human uroepithelial cells in view of the recognition in the art, as evidenced by the Gorman et al reference, that treatment of either the microbial or epithelial cells with Taurolidine resulted in significant reductions in adhering microorganisms.

One of ordinary skill in this art would be motivated to combine the teaching of the Jones et al reference with that of the Gorman et al reference in a rejection of the claims under 35 U.S.C. 103 since both references discuss anti-adherence activity of microorganisms to epithelia cells by treatment with Taurolidine.

10. Applicant's arguments with respect to Claims 18-35 have been considered but are moot in view of the new ground(s) of rejection.

Summary

11. All the pending claims are rejected.

Examiner's Telephone Number, Fax Number, and Other Information

12. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit out website at **www.uspto.gov** and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reach on (703) 308-4624. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

E. White

E.White

James O. Wilson
Supervisory Primary Examiner
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